HFA-305

MINUTES OF A FEEDBACK MEETING

1478 '99 NOV 18 A9:

October 8, 1999
10:00am - 11:00am
9201 Corporate Blvd., Rockville, MD
Conference Room S400

Warner-Lambert Company
Paul Okarma, Ph.D, Director, Regulatory Affairs
Lori Kumar, Director, R&D, Oral Care
Michael Lougner, Manager, Public Affairs
Scott Harper, Ph.D, Technology Development, Oral Care
Lynn Lee Shong, Category Manager, Global Oral Care
Judith Sills, Pharm. D., Senior Director, U.S. Regulatory Affairs and Global Product Safety
Richard D'Souza, Vice President, R&D, Oral Care, Upper Respiratory
David Long, Associate Council, Regulatory Affairs

and

Food and Drug Administration
Division of OTC Drug Products, HFD-560
Charles J. Ganley, M.D., Director
Linda M. Katz, M.D., M.P.H., Deputy Director
Robert L. Sherman, Review Biologist
Gerald M. Rachanow, Regulatory Counsel
Debbie Lumpkins, Team Leader, Microbiologist
Rosemarie Neuner, M.D., M.P.H., Medical Officer
Cazemiro R. Martin, Review Chemist
Stephanie Mason, IDS Reviewer
Kerry Rothschild, Project Manager

Division of Dermatologic and Dental Drug Products, HFD-540
Frederick N. Hyman, D.D.S., M.P.H., Dental Reviewer

Other Attendees
Patrice B. Wright, Ph.D., Director, Pharmacology & Toxicology, Consumer Healthcare Products Association
Carrie Hay Gregory, Manager, Legal & Regulatory Affairs, CTFA
Michael Fagan, Public Relations, New York
Sybil Mead, News Editor, The Rose Sheet, FDC Reports

Subject: Oral Health Care

Purpose: To reach agreement on the regulatory process to market a combination drug product making both anticaries and antiplaque/antiginivitis claims.

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Paul Okarma opened the meeting with a brief discussion of a discrepancy between the dosing for oral rinses in the anticaries final monograph and the Dental Plaque Subcommittee's (the Subcommittee) recommended dosing for antigingivitis, antiplaque oral rinses in that ongoing rulemaking. Dr. Okarma stated that Warner-Lambert wishes to market a combination mouthrinse product making anticaries and antiplaque/antigingivitis claims. He noted that the Subcommittee had agreed that an anticaries agent combined with an antiplaque/antigingivitis agent would be a rational combination.

Dr. Okarma stated that Warner-Lambert would submit a study supporting amendment of the anticaries final monograph to allow for a dosing regimen for fluoride mouthrinses consistent with the Subcommittee's recommended dosing for antiplaque/antigingivitis mouthrinses. If the agency agrees that the alternative dosing is safe and effective, Warner-Lambert requests that the agency issue a notice of enforcement policy permitting interim marketing of the combination product during the period it takes to formally amend the anticaries final monograph.

Discussion points:

Citing previous examples of published notices of enforcement policy, Warner-Lambert requested agreement on a regulatory process that would allow the interim marketing of a combination anticaries and antiplaque/antigingivitis mouthrinse product. This process would permit marketing of the combination mouthrinse during the time period necessary to amend the anticaries final monograph to allow a dosing regimen consistent with the Subcommittee's recommended dosing for antiplaque/antigingivitis mouthrinses.

Warner-Lambert noted that the Subcommittee had found the ingredients in Listerine Mouthrinse to be safe and effective and had agreed that an anticaries agent combined with an antiplaque/antigingivitis agent would be a rational combination. Warner-Lambert agreed to submit data and petition to amend the anticaries final monograph, but declined to discuss the details of any studies at this meeting.

Agency representatives responded to the following questions:

1. Once the studies supporting an additional dosing regimen are reviewed and accepted, will the agency agree to publish an enforcement policy allowing marketing of a combination mouthrinse product during the period that it takes to formally amend the anticaries monograph?

Agency response:

With no information concerning studies that the sponsor plans to submit to support amendment of the anticaries monograph, the agency cannot make any commitments regarding future actions at this time. Although a potential pathway to market the combination mouthrinse could be a notice of enforcement policy, the agency recommends that the sponsor follow the established procedure and submit a citizen petition including data supporting amendment of the anticaries monograph to include an additional dosing regimen for oral rinses and allow for the marketing of an anticaries and antiplaque/antigingivitis mouthrinse.

Although the sponsor cites a 1992 enforcement policy allowing marketing of a combination tooth desensitizer/anticaries product, neither the oral healthcare nor anticaries monographs were final rules at that time. Because the anticaries monograph is a final rule, amendment of the monograph would not necessarily require more time than the notice and comment period required before publication of an enforcement policy to allow interim marketing.

2. The Panel recommended that an antiplaque/antigingivitis agent plus an anticaries agent would be a rational combination product. Does the agency agree that this is an acceptable combination?

Agency response:

Although the Panel, without any data, agreed in principle that an antiplaque/antigingivitis agent plus an anticaries agent would be a rational combination, the agency is still assessing that recommendation. The agency currently has no data on the safety and effectiveness of the proposed combination. The first step in marketing such a combination product would be to establish that the proposed combination is generally recognized as safe and effective.

Agreements:

1. The sponsor will submit data to support amendment of the anticaries final monograph to include an additional dosing regimen for fluoride mouthrinses and to allow for a combination product making antiplaque/antigingivitis and anticaries claims.

2. The sponsor will request a feedback meeting to obtain agency comments on any submitted protocols.

Robert L. Sherman

Robert L. Sherman
Meeting Chairperson

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: NOV 16 1999

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 81N-033A

TO: Dockets Management Branch, HFA-305

☐ The attached material should be placed on public display under the above referenced Docket No.

☐ This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment